

IN THE UNITED STATES DISTRICT COURT FOR THE  
MIDDLE DISTRICT OF TENNESSEE  
NASHVILLE DIVISION

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RUTH SMITH, Individually and as Widow	)
for the Use and Benefit of Herself and the	)
Next of Kin of RICHARD SMITH, Deceased,	)
	)
Plaintiff,	)
	)
-against-	)
	)
PFIZER INC., PARKE-DAVIS,	)
a division of Warner-Lambert Company	)
and Warner-Lambert Company LLC,	)
WARNER-LAMBERT COMPANY,	)
WARNER-LAMBERT COMPANY LLC and	)
JOHN DOE(S) 1-10,	)
	)
Defendants.	)
-----X	

Case #: 3:05-00444  
Judge Trauger

STATEMENT OF PLAINTIFF'S EXPERT  
RONALD WM. MARIS, Ph.D.

Hello, my name is Dr. Ronald Maris. As you have heard, I am a professor at the University of South Carolina School of Medicine who has been studying and trying to prevent suicides for over 40 years. You may be wondering if I am related to former Yankee and St. Louis baseball player, Roger Maris. The short answer is "yes," distantly. He and I were the same age and I went to the University of Illinois on a track and basketball scholarship.

I am going to offer my opinions in the following 13 areas that Mr. Lanier told you about in his opening statement. As a general outline, I plan on giving some background information on suicide and Neurontin first. Then, I plan on talking about Richard Smith. Lastly, I will let you know how I concluded that Neurontin contributed to Richard Smith's suicide. My opinions are as follows:

1. Many Factors Cause a Suicide
2. Prescription Drugs Can Cause Suicide
3. Neurontin is a Powerful Mood-Altering Drug

4. FDA Concluded in 2008 that Neurontin Was Linked to Suicides
5. Neurontin Currently Carries a Suicide Warning
6. Neurontin Can Cause Suicides
7. Richard Smith Had Severe Pain
8. Neurontin Was Never Approved to Treat Richard Smith's Type of Pain
9. Richard Smith Was Taking Neurontin When He Committed Suicide
10. Richard Smith Was at Low Risk for Suicide
11. Richard Smith Began Having Mood/Behavior Changes After Taking Neurontin
12. Richard Smith Did Not Kill Himself Because of his Chronic Physical Pain
13. Neurontin was a Substantial Contributing Factor to Richard Smith's Suicide

Those are the 13 areas that I intend on talking to you about. I will try and address these points in order.

1. Many Factors Cause A Suicide.

As background, there are just over 30,000 suicides in the United States every year and about 1 million suicides world-wide. Suicides are caused by a variety of different interacting psychiatric and physical conditions, genetic influences, social and economic factors, problems with substance abuse, medications, availability of guns and other lethal methods, and so on. Thus, suicides usually have more than one cause. Put differently, suicides are multifactorial.

Suicide researchers have identified common "risk factors" for suicide. A "*risk factor*" is a condition that makes you more likely to commit suicide than another person who does not have the risk factor. Based on my case-control studies of suicide, I have identified 15 statistically significant risk factors (there could be up to 100 or so total risk factors). My procedure for identifying suicide factors is part of what is called "*evidence-based psychiatry*." These suicide risk factors are:

1. Depressive and Psychiatric Disorders
2. Alcoholism or Substance Abuse
3. Suicidal ideation, Talk, Preparations
4. Prior Suicide Attempts
5. Access to Guns or other Lethal Methods

6. Isolation & Loss of Social Support
7. Hopelessness, Rigid Thinking
8. Being an Older White Male
9. Family History of Suicide
10. Work Problems, including Unemployment
11. Marital or Sexual Problems
12. Stress and/or Negative Life Events
13. Anger, Aggression, Impulsivity, Serotonergic Dysfunction<sup>1</sup>
14. Physical Illness
15. Suicidal Careers (i.e. multiple risk factors & repeating factors over time)

There are also factors that protect or tend to prevent an individual from committing suicide. Among the most common protective factors are:

1. Strong religious beliefs
2. Supportive, extensive family life
3. Positive sense of self-worth

2. Prescription Drugs Can Cause Suicides.

In the past 10 years, it has become clear that many prescription drugs can cause suicides. I worked as part of a research group based at Columbia University that analyzed anti-depressant drugs such as Prozac. This research group concluded that anti-depressant drugs were linked to suicides in adolescents and children. The FDA adopted these conclusions and all anti-depressants today carry a suicide warning. Given this relatively recent data, it is clear that some prescription drugs are also risk factors for suicide.

3. Neurontin is a Powerful Mood-Altering Drug

Neurontin (also known by its scientific, generic name gabapentin) is part of a class of drugs called anti-convulsants which are used to treat people who suffer seizures brought on by epilepsy. The drug was designed to work by changing the levels of neurotransmitters in the brain. Neurontin was initially approved by the FDA as an adjunctive or add-on medication to be used in conjunction with other approved medications for the treatment of seizures from epilepsy. Neurontin was subsequently approved by the FDA for use to treat pain from shingles or post-herpetic neuralgia.

4. FDA Concluded in 2008 that Neurontin Was Linked to Suicides

In January 2008, the FDA sent out an alert to healthcare providers informing them of the FDA's preliminary conclusion that anti-epileptic drugs including Neurontin were linked to suicide. **Exhibit 3849.** In May 2008, the FDA released its finding in a Statistical Review that concluded that Neurontin (and other anti-epileptic drugs) are

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<sup>1</sup> Obviously, in the Richard Smith case, I claim a drug was one of the major causes of his suicide. Neurontin affects the neurotransmitter Serotonin, which can make a person more suicidal.

linked to higher suicide risk (about twice as high as patients not taking Neurontin). The FDA's actual conclusion is as follows:

In conclusion, antiepileptic drugs are associated with increased risk of suicidality relative to placebo in randomized placebo-controlled trials. The effect appears consistent among the group of 11 drugs.

**Exhibit 2808.**

5. Neurontin Now Carries a Suicide Warning.

In December 2008, the FDA mandated an explicit warning to doctors and patients warning them of the increased risk for suicide for patients taking Neurontin. **Exhibit 2018.** The current label for Neurontin carries an explicit suicide warning. **Exhibit 2009.**

6. Neurontin Can Cause Suicides.

In the last few years, there have been an increasing number of published scientific studies that have shown a link between Neurontin and suicide. For example, in 2007, two scientists (Collins and McFarland<sup>2</sup>) from Oregon studying Neurontin concluded that the risk of suicide completion was 2.6 times higher for people with bipolar disorder who were taking Neurontin, as opposed to bipolar disorder patients taking another drug, called lithium. This result was statistically significant; meaning that there was a very small probability that this result was a "fluke" or the result of chance alone. **Exhibit 460.**

Two other recent studies have reached similar conclusions. One study based in Denmark (Olesen et al.<sup>3</sup>) came out just 2 months ago. It examined all Danish patients who took anti-epileptic drugs from 1997 to 2006. While the results for Neurontin specifically were not statistically significant, the study basically replicated the findings of the FDA that all anti-epileptic drugs generally increased the risk of suicide. **Exhibit 5869.**

Another impressive study published in the **Journal of the American Medical Association**<sup>4</sup> last month by a group of Harvard researchers (Patorno et al.) concluded that there was, in fact, a statistically significant increased risk (about 1 and 1/2 times higher) of suicidal acts for patients taking Neurontin. The study examined over 130,000 people who took Neurontin and analyzed attempted suicides, completed suicides and violent deaths. **Exhibit 5870.** Of particular relevance to this case was that the study found an increased risk of suicide in older patients ... like Richard Smith.

After reviewing the FDA's conclusions about suicide and antiepileptic drugs, and seeing them confirmed in a number of top scientific studies and respected peer-reviewed journals, Neurontin is clearly a significant risk factor for suicide.

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<sup>2</sup> **Journal of Affective Disorder.**

<sup>3</sup> **Pharmacoepidemiology and Drug Safety**, Wiley: 2010.

<sup>4</sup> **JAMA** 303 (14): 1401-1409.

When I considered these (and other)<sup>5</sup> scientific studies, I investigated whether there is an explanation as how Neurontin alters brain chemistry that would explain this link between Neurontin and suicide. I reviewed the expert reports in this case as well as the medical literature in this field. Neurontin (or gabapentin) increases a neurotransmitter in the brain called GABA. This increase in GABA, in turn, decreases brain chemicals (most notably monoamines like serotonin and norepinephrine). A decrease in serotonin (and serotonergic dysfunction in general) has been linked to suicidal behavior,<sup>6</sup> especially for modern anti-depressant drugs (such as the 9 studied for the FDA and Columbia University). This interaction of GABA and serotonin is one likely explanation of the link between Neurontin and suicide.

7. Richard Smith Had Severe Pain.

Richard Smith committed suicide on May 13, 2004. He was a relatively healthy 79 year-old man, except for some nagging orthopedic problems he had coped with for years. Mr. Smith was married for over 50 years to Ruth Smith and had four daughters. He had arthritis and a series of joint problems; he had a knee replacement in 1993; a hip replacement in 1996; another knee replacement in 1998; and back surgery in April 2003. Prior to and after these surgeries, Smith had substantial amounts of pain in these joints. A brief summary of Richard Smith's medical history is as follows:

11/16/1993	Left Knee Replacement	(Exh. 87 @ p. 69)
5/2/1996	Left Hip Replacement	(Exh. 87 @ p. 62)
6/22/1998	Right Knee Replacement	(Exh. 87 @ p. 49)
2/27/2003	Wants Back Surgery ASAP	(Exh. 43 @ p. 35)
3/5/2003	"Out of his mind" with back pain	(Exh. 43 @ p. 45)
4/1/2003	Back surgery – Laminectomy	(Exh. 74 @ p. 49)
5/2/2003	Daughter reports that Richard Smith wishes he could die because of pain	(Exh. 74 @ p. 11)
10/13/2003	Doing well. Pleased with results of surgery	(Exh. 74 @ p. 13)
1/29/2004	Reports pain is like razor blades in his legs	(Exh. 64 @ p. 17)
3/9/2004	Discussed surgery with Dr. Mackey. Receives Neurontin script. Referral for psychiatric evaluation to rule out dementia.	(Exh. 71 @ p. 22)
5/5/2004	Pain in legs and buttocks.	(Exh. 74 @ p. 14)
5/6/2004	Physical therapy. No change in pain.	(Exh. 88 @ pp. 28-29)
5/13/2004	Suicide	

Of particular note are several notes in his medical record about the levels of pain that he was suffering.

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<sup>5</sup> For example, see my complete list of citations in my expert report; like Petroff, 2000, Forchetti, 1981, Schlicker, 1985, Nishikawa, 1985, and others.

<sup>6</sup> For example, see my 1986 book, **Biology of Suicide**, and the research of Marie Asberg in Sweden.

8. Neurontin was Never Approved to Treat Richard Smith's Type of Pain.

Richard Smith was not an epileptic. He never suffered any seizures. He never had shingles. He was prescribed Neurontin for his orthopedic joint pain. Neurontin was never approved by the FDA to treat these conditions.

9. Richard Smith Was Taking Neurontin When He Committed Suicide.

Richard Smith was prescribed Neurontin on 2 or 3 occasions. It appears that he filled his first prescription on March 9, 2004,<sup>7</sup> after he was prescribed Neurontin by neurosurgeon, Dr. Edward Mackey, on that same day. He was prescribed 600 mg. (300 mg., two times a day) and received 60 pills of Neurontin. Later that month, on March 24, 2004, Richard Smith's doctor, Dr. McCombs, increased the dosage of Neurontin to 900 mg. (300 mg., three times a day). Richard Smith was also given samples of Neurontin, most likely by Dr. Mackey, Dr. McCombs or his nurse, Pamela Krancer. At the time of his death, there were numerous sample boxes of Neurontin found in his house. **Defense Exhibit 210.**

Richard Smith consistently and repeatedly reported to many different people that he was taking Neurontin in the last 2 months of his life. For example,

- On March 24, 2004, Richard Smith's doctor (Dr. McCombs) instructs him to increase his Neurontin usage to 3 times a day.
- On April 14, 2004, Richard Smith reports to his physical therapist that he is taking Neurontin.
- On May 5, 2004, Richard Smith spoke to Dr. McCombs and told him that Neurontin was not providing him with pain relief.
- On May 9, 2004, Richard Smith told his son-in-law, Wes Carnahan, who was a pharmacist, that Neurontin was making him feel "loopy."
- On May 10, 2004, Richard Smith tells his dentist (Christopher Wood) – that Neurontin "*makes me feel weird and is not helping.*"

10. Richard Smith was at Relatively Low Risk of Suicide Prior to Taking Neurontin.

Of the 15 most significant risk factors for suicide that I mentioned above, Richard Smith had only about half of them.<sup>8</sup> Significantly, several of these risk factors (depression, suicidal thoughts, and hopelessness) were triggered and/or made worse by Neurontin usage. Roughly speaking, Richard Smith was a 5 on a 10 point scale for suicide risk. Many people have a few suicide risk factors (like being an older white male), but actual suicides tend to have all or most of the risk factors. Richard Smith also possessed numerous personal characteristics that are protective from suicide. For example, he had a strong religious background and belief as a Church of Christ minister that suicide was a sin and had given sermons against suicide. He had a loving wife of

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<sup>7</sup> Neurontin prescriptions were suggested on 5/5/03 by Dr. McCombs and on 1/5/04 by Dr. Brent, but Richard apparently never filled or took those prescriptions.

<sup>8</sup> Most suicides have all or most of the suicide risk factors.



over 50 years and 4 loving daughters. He had a strong sense of self-worth and a quiet self-confidence. He was a music director in his church and loved life.

In my research and clinical experience, most individuals who commit suicide tend to have many more risk factors than Richard Smith did. For example, the famous author, Ernest Hemingway, had all 15 risk factors (he was a 10 on the risk scale) when he committed suicide. Thus, absent some acute "trigger" factor, I would not have expected Richard Smith to commit suicide.

11. Richard Smith Began Having Mood/Behavior Changes After Taking Neurontin.

After taking Neurontin, Richard Smith began to exhibit "what is called "ego-dystonic behavior;" in ordinary English, he did not act like himself. At various points in time just prior to his suicide, after starting to take Neurontin, Richard Smith reported to people that he felt "loopy," "weird," or "strange" and he began exhibiting a more withdrawn personality and was less outgoing than before. This change in behavior or character is typical of drug-induced suicides.<sup>9</sup> **Exhibit 96 & 97.**

In the two months prior to his suicide, Richard Smith began to exhibit the classic signs of depression: a sad mood, inability to take interest in activities that used to give him pleasure, insomnia, being slowed down, fatigue, thoughts about dying, and so on. Prior to his Neurontin prescription, Richard had little to no signs of depressed behavior and attitudes.

Richard Smith began to feel hopeless **only** after he took Neurontin. In fact, he told his dentist, Christopher Wood – just three days before his suicide – that "*an end to pain seemed to be hopeless.*" These feelings of hopelessness are one of the most dangerous precursors to suicide. When a patient is hopeless, they see no alternative to resolve their life problems, except to die. Although Richard Smith had been in pain before taking Neurontin, he never said (as he did in his suicide note on 5/13/04) "*Forgive me, I cannot go on like this.*" **Exhibit 109.**

Given his long-standing joint pain and problems sleeping, Richard Smith had been given some anti-depressants before he took Neurontin on March 9, 2004.<sup>10</sup> There is mention in the medical records by Dr. Berklacich in February 2003, that Richard Smith had some pain, depression, and sleep troubles. Again, on May 2, 2003, there was one report by Smith's daughter that "*he wishes he could die,*" because of depression and pain. Thus, there is evidence that Richard Smith had some depression and thoughts of dying (not suicide) before he ever took Neurontin on March 9, 2004. However, he was never hopeless before taking Neurontin and he only made a suicide attempt after starting Neurontin. That is, Neurontin made Richard's depression much worse. So much worse

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<sup>9</sup> Another drug-related adverse event can include emotional blunting.

<sup>10</sup> For example, Smith got Elavil from his family doctor Cato on 5/10 & 22/01 to help him sleep. Again, in May of 2003 Richard was given the antidepressant Lexapro by Dr. Cato and Desipramine in June and July of 2003 for sleep problems and pain.

that for the first time in his life he seriously considered suicide as a resolution to his problems.

12. Richard Smith Did Not Kill Himself Because of his Chronic Physical Pain.

Despite his suicide note that "*pain has taken over my mind and body*," Richard Smith did not commit suicide because of his chronic physical pain. Richard Smith had lived with chronic pain for many, many years before starting Neurontin on March 9, 2004. He had suffered several years of knee pain before he had left knee replacement in 1993. Richard Smith also suffered from significant right knee pain and hip pain which were also severe enough to ultimately require joint replacement. Richard Smith had endured significant back pain in 2003 without committing suicide. As his own physician (Dr. Mackey) noted, there are a lot of people in the United States who suffer chronic pain, but most of them do not commit suicide because of the pain. Richard Smith's experience with chronic pain for 10-20 years prior to his suicide greatly reduces the possibility that pain was the cause of his suicide. Neurontin compromised Richard Smith's prior ability to cope with his physical pain.

13. Neurontin was a Substantial Contributing Factor in or Cause of Richard Smith's suicide.

In reviewing the medical records in this case, the testimony from the witnesses, the scientific literature surrounding Neurontin, the FDA's conclusion that Neurontin is linked to suicide and the scientific literature of suicide, it is clear that Neurontin was a substantial contributing factor in or cause of Richard Smith's suicide.<sup>11</sup>

In arriving at this conclusion, I have applied the most significant risk factors associated with suicide outcome and systematically analyzed whether or not they are applicable to Richard Smith's suicide. If the risk factor is applicable, I have ruled it in (yes) as a possible cause. If the risk factor is not applicable, I have ruled it out (no) as a possible cause Richard Smith's suicide.

A summary of the analysis follows:

1.	Depressive or Psychiatric Disorder	Yes <sup>12</sup>
2.	Alcoholism, Drug or Substance Abuse	No
3.	Suicidal Thoughts, Talk, Preparation	Yes <sup>13</sup>
4.	History of Suicide Attempts	No
5.	Access to Firearms or Other Lethal Method	Yes
6.	Isolation & Loss of Social Support	No
7.	Hopelessness	Yes <sup>14</sup>

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<sup>11</sup> All that is required is that Neurontin was one of the causes of Richard Smith's suicide, not the only cause. It was a necessary, but not sufficient condition for his suicide.

<sup>12</sup> Induced or made worse by Neurontin.

<sup>13</sup> Richard Smith only thought seriously about suicide and made a violent suicide attempt after taking Neurontin.



8.	Being an Older White Male	Yes
9.	Family History of Suicide	No
10.	Work Problems, inc. Unemployment	Yes
11.	Marital or Sexual Problems	No
12.	Stress and/or Negative Life Events	Yes
13.	Anger, Aggression, Impulsivity and/or Irritability	No? <sup>15</sup>
14.	Physical Illness, Chronic Pain	Yes
15.	Suicidal Careers, Co-Morbidity, Repetition 1-14	Yes
16.	Neurontin	Yes

As a result of this process, commonly referred to as a "*differential diagnosis*," I conclude that Neurontin was a significant contributing factor in or cause of Richard Smith's suicide.<sup>16</sup>

Thus, in terms of differential diagnosis, Richard Smith's taking Neurontin was the *coup de grace* which caused his suicide. It was the "trigger" or acute factor that potentiated, induced, or made worse the other suicide risk factors.

I believe that gabapentin pushed Richard Smith over the edge. He changed dramatically after taking Neurontin. Gabapentin was the trigger that destroyed Richard Smith's considerable prior ability to cope with life's problems and to fend off suicide.

All of my opinions today are offered to a reasonable degree of scientific certainty.

### Disclosure

In order for you to be able to assess my credibility, I want to disclose to you how much I have been paid for my work in this case and any other relevant information. I have been

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<sup>14</sup> Smith never felt hopeless before March 9, 2004.

<sup>15</sup> Smith likely did become more impulsive as a result of Neurontin causing a serotonergic dysfunction.

<sup>16</sup> The use of differential diagnosis to determine if Neurontin was a cause of Richard Smith's suicide is somewhat complicated. Usually, in Psychiatry, differential diagnosis is used to "*rule-out*" competing diagnoses or causes of mental disorder. The end result is that the psychiatrist hopes usually (there can be "co-morbid" diagnoses) to end up with one appropriate diagnosis. Here, however, I **both rule-out and rule-in** suicide risk factors. This is appropriate, since suicide has many causes (not one) and is "multifactorial," as noted above. Neurontin was a major proximate suicide risk factor, but not the only suicide risk factor in Richard Smith's life

However, in a real sense, I am "*ruling-out*" non-Neurontin risk factors as a cause of Richard Smith's suicide. For one thing, Richard lived with his non-Neurontin risk factors (like access to guns, being an older white male, not being able to work like before, stress, and chronic pain) until after he took Neurontin. For another, many of the non-Neurontin suicide risk factors (like depression, having suicide ideas, and hopelessness) were the result of his taking Neurontin or were made worse by his taking Neurontin.

paid \$400 dollars an hour for investigative work and \$500 per hour for testifying in this case. As of the date of this trial, I have been paid a total of \$62,000.00.

I have testified on behalf of Plaintiffs in about two dozen prescription drug cases, in which Plaintiffs have alleged that a prescription psychiatric drug has caused suicide. The drugs I testified about included Neurontin (gabapentin), Paxil (paroxetine), Zoloft (sertraline), Prozac (fluoxetine), Cymbalta (duloxetine), Effexor (venlafaxine), Wellbutrin (bupropion), and Accutane.

I have consulted on approximately 218 civil and criminal cases in the last 30 years. (52% for the plaintiff and 48% for the defense).

#### Summary of My Opinions.

Because my testimony was so long, I want to briefly summarize my opinions to you before I go.

1. Many Factors Cause A Suicide
2. Prescription Drugs Can Cause Suicide
3. Neurontin is a Powerful Mood-Altering Drug
4. FDA Concluded in 2008 that Neurontin Was Linked to Suicides
5. Neurontin Currently Carries a Suicide Warning
6. Neurontin Can Cause Suicides
7. Richard Smith Had Severe Pain
8. Neurontin Was Never Approved to Treat Richard Smith's Type of Pain
9. Richard Smith Was Taking Neurontin When He Committed Suicide
10. Richard Smith Was at Low Risk for Suicide
11. Richard Smith Began Having Mood/Behavior Changes After Taking Neurontin
12. Richard Smith Did Not Kill Himself Because of his Chronic Physical Pain
13. Neurontin was a Substantial Contributing Factor to Richard Smith's Suicide

Thank you for your attention and patience.

Respectfully submitted,

THE LANIER LAW FIRM, P.C.



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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the forgoing was served via the Court's ecf filing system on this 27th day of April, 2010 on the following:

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